III. Remarks

Responsive to the Office Action mailed July 9, 2009, and further to the Reply mailed September 26, 2009, the present paper is filed subsequent to an Examiner's Interview on November 18, 2009. Applicants' Interview Summary is provided below.

By the present paper, claim 2 is cancelled without prejudice or disclaimer of subject matter therein, and claims 3, 24 and 25, and 36 are amended. Claims 3 - 14, 16 - 26, and 31 - 36 are in the Application.

Entry of the claim amendments and reconsideration of the Application are respectfully requested.

A. Applicants' Interview Summary

An interview with the Examiner was held on November 18, 2009. The participants were Examiner Channavajjala, Applicant Sergio Nacht, Ph.D., and Applicants' attorney, Louis C. Paul.

Claim 36 and the disclosure of applied WO 01/912726 were discussed. Agreement was reached that amendment of claim 36 to include the limitations of claim 2 and amendment of claim 3 to depend from amended claim 36 would advance prosecution of the Application. It was further agreed that Applicants would amend claim 36 to recite that the active ingredient in the first and second emulsion are different. It was also agreed that Applicants would amend the specification to expressly include portions of subject matter incorporated by reference relating to loading of active ingredients of the delivery system.

Applicants explained that Carbomer as taught in the prior art is a linear polymer that is not cross-linked. Carbomer swells, thereby acting as a thickener in cosmetic or pharmaceutical formulations for topical administration.

In contrast, the polymeric delivery systems of the present invention are cross-linked, non-swellable polymers. More particularly, polymeric delivery systems within the scope of the present invention have a plurality of micropores that imbibe and entrap active ingredient, thereby causing the active ingredient to be released in a controlled manner. Carbomer does not provide for such controlled release.

Applicants explained that, when contacted with a liquid, the active ingredient imbibed in the micropores of the polymeric delivery system will be partitioned between the delivery system and the carrier liquid. If the polarity, or lipophilicity, of the liquid is such that the liquid is a very good solvent for the active ingredient, the partitioning will strongly favor the liquid and the majority of the active ingredient will be precipitously lost – or "dumped" – from the delivery system to the liquid. Thus, where the carrier is a very good solvent for the active ingredient – the majority – if not all – of the active ingredient will be lost from the delivery system, causing essentially the entire amount of active ingredient to be delivered immediately. In this case, delivery is not in a controlled manner, as Applicants use that term.

Applicants further explained that replacing Carbomer – as taught in the secondary references, US 7,060,732 (Vishnupad *et al.*), US 5,955,109 (Won *et al.*), EP 0 306 236 (Katz *et al.*) – with the non-swellable, crosslinked polymeric delivery systems of the present invention, would result in dumping of the active ingredient and uncontrolled release. In the prior art formulations taught in the secondary references, the non-swellable, crosslinked polymeric delivery system would thus serve no purpose and would be little more than inert, empty, microporous particles.

B. Amendments to the Specification

The specification is amended at paragraph [0053] to insert text from column 3, line 64 to column 4, line 5, of United States Patent 5,955,209, which was incorporated by reference.

The specification is further amended at paragraph [0054] to insert text from column 5, lines 3 to 10 of United States Patent 4,690,825, which was incorporated by reference. The specification is further amended to insert text from column 7, lines 57 - 62 of United States Patent 5,955,109, which was also incorporated by reference.

C. The Claim Amendments

Claim 36 is amended as proposed by the Examiner to incorporate the limitations of claim 2, now cancelled, which previously depended from claim 36.

Claim 36 is further amended as proposed by the Examiner to recite that the non-swellable and cross-linked polymeric delivery system includes 5% to 60% by weight of active ingredient that is not a retinoid, and when a retinoid is an active ingredient, the delivery system includes about 1% to 20% of the retinoid. Literal support in the specification for the amendment is found in the text expressly incorporated *supra*.

Claims 3 and 24 are amended to correct their dependency required by cancellation of claims 2 and 3.

Claim 25 is amended to correct its dependency required by cancellation of other claims, and further to make it consistent with amended claim 36 from which it now depends. Applicants respectfully submit that support for the amendment can be found at least in the claims as filed.

Applicants respectfully submit that the claim amendments do not introduce new matter into the Application.

Conclusion

Applicants have previously argued that the Office has not identified any motivation to use "microsponges" (or other similar polymeric delivery systems) in a single-phase "gel" formulation as taught by WO '726 and, therefore, incorporate in their entirety Applicants' arguments from their prior responses.

Based on the foregoing amendments and remarks, Applicants respectfully submit that the claims are now in condition for allowance, which allowance is earnestly solicited, in particular given the advanced age of one of the inventors who is over 70 years old. If, in the view of the Examiner, a telephone conference would advance prosecution of the Application, the Examiner is invited to telephone the undersigned attorney.

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Respectfully submitted,

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